

REMARKS

This amendment is responsive to the Final Office Action dated August 25, 2005, in which Claims 1-20 were rejected. Claims 1 and 11 have been amended. Accordingly, Claims 1-20 are pending in the application, and are presented for reconsideration and allowance.

More specifically, claims 1-20 are rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 6,382,125 to Tamura. Furthermore, claims 1-20 are rejected under 35 USC 102(e) as being anticipated by U.S. Patent No. 6,536,370 to Paton et al. Based on the following remarks, the Examiner is asked to reconsider the rejection of claims 1-20.

According to the present invention as recited in independent claims 1 and 11, an environmental sensitive label includes at least one irreversible cumulative time-temperature indicator and at least one irreversible thermal event indicator. In an important aspect, the cumulative time-temperature indicator and the thermal event indicator each provides an independent verification of product performance. The cumulative time-temperature indicator integrates the time-temperature profile of the product under expected ambient storage conditions. The rate of change of the cumulative time-temperature indicator is such that it signals at some time that the product has reached its prime and will start to degrade. The separate thermal event indicator provides fast feedback to the consumer that the product has been exposed to very high temperatures that exceed the thermal limits of the product. In such cases, fast action should be undertaken to preserve the product. The important aspect is that these two indications are separated in two distinct indicators such that actuation of one indication does not compromise the other.

Turning to the first rejection, that is, the rejection of claims 1-20 under 35 USC 102(e) as being anticipated by Tamura, a single temperature indicator 4 is shown in Tamura on a temperature control material (label) 1 (see FIG. 3A, col. 9, lines 16-31). In its usage, the reflectance of the temperature indicator changes in a known way over time during exposure to a given temperature such that, knowing the elapsed time of exposure of the material to the (unknown) temperature, the temperature may be determined by reference to the reflectance value. For example, at the beginning of temperature control, the

temperature indicator is initialized by heating and quenching with a thermal head (col. 9, lines 31-48), and a bar code 3 with the start time of control is imprinted on the label 1 (col. 5, lines 27-46). Then, at the end of temperature control, a reader 10 (FIGS. 7 and 8, col. 10, lines 1-16) takes readings of the reflectance of the temperature indicator and the start time from the bar code, computes the elapsed time from the start time and the time of measurement, and then inputs the reflectance and elapsed time into a set of table values (e.g., FIG. 9) to determine the environmental temperature to which the temperature indicator was exposed. In addition, if the temperature indicator 4 is exposed to a temperature higher than its glass transition temperature, indicating an abnormal temperature environment that departs from the above-noted period of temperature control, then the temperature indicator acts as an alarm by quickly changing its color.

The important observation regarding Tamura is that there is no suggestion or teaching in Tamura of two separate indicators as required by the present claims, that is, at least one cumulative time-temperature indicator and at least one thermal event indicator, where each provides an independent verification of product performance. Indeed, the use of a single indicator, both for temperature control and as an alarm, means that the indicator is incapable of providing an independent verification of product performance under these two circumstances. In other words, once used to register an alarm, the reflectance of the indicator would be unusable for temperature control, at least until it is re-initialized. This is exactly the type of prior art over which the present invention is an improvement. Moreover, there is nothing in Tamura that suggests or discloses a radiation indicator (dependent claims 2 and 12), a freshness date indicator (dependent claims 3 and 13), a set of instructions (dependent claims 6 and 16), the integration of time and temperature in the cumulative time-temperature indicator – remembering that time is externally calculated in Tamura - (dependent claims 7 and 17), a bull's eye indicator (dependent claims 8 and 18), or a calibration ruler (dependent claims 9, 10, 19 and 20).

It is axiomatic that for prior art to anticipate under § 102(b) it has to meet every element of the claimed invention. *Hybritech Inc. v. Monoclonal Antibodies, Inc.* 231USPQ 81, 90 (Fed. Cir. 1986). Anticipation under 35 U.S.C. Section 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Rockwell International Corp. v. United States*

47USPQ2d 1027, 1031 (Fed. Cir. 1998). The foregoing remarks indicate that each claim includes one or more claimed elements that are not to be found or suggested by the Tamura reference. For anticipation to be found, all of the claimed elements must be found in Tamura. Since that is not the case with respect to each and every one of the claims 1 – 20, the Examiner is respectfully asked to withdraw the rejection of these claims under 35 U.S.C. 102(b) as based on Tamura.

Turning now to the second rejection, that is, the rejection of claims 1-20 under 35 USC 102(e) as being anticipated by Paton et al, an indicator device in Paton et al. is used for measuring an elapsed time in an environment where the atmospheric composition is controlled and does not vary (col. 3, lines 55-58). In particular, the temperature, humidity and gas composition are held constant (within certain tolerances) while an object is processed in the environment. The indicator device includes a substance sensitive material having a color that varies in accordance with exposure (elapsed time) to a specific substance in the environment, and specifically to a constant level of humidity in the environment, i.e., the longer in the constant humidity the more the color changes (col. 4, lines 6-11 and 38-41). From the color, therefore, the elapsed time of the object in the environment can be determined.

In Paton et al., however, there is no suggestion or teaching of an indicator device, or a substance sensitive material used on the device, that is intended and used to sense temperature or a thermal event. Accordingly, there is nothing in Paton et al. to disclose or suggest either of the separately claimed indicators, namely, the irreversible cumulative time-temperature indicator or the irreversible thermal event indicator recited in the present independent claims 1 and 11. Moreover, there is nothing in Paton et al. that suggests or discloses a radiation indicator (dependent claims 2 and 12), a freshness date indicator (dependent claims 3 and 13), a set of instructions (dependent claims 6 and 16), the integration of time and temperature in a cumulative time-temperature indicator (dependent claims 7 and 17), a bull's eye indicator (dependent claims 8 and 18), or a calibration ruler (dependent claims 9, 10, 19 and 20).

As stated above, it is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention. Thus, anticipation under 35 U.S.C. Section 102(e) requires the disclosure in a single piece of prior

art of each and every limitation of a claimed invention. The foregoing remarks indicate that each claim includes one or more claimed elements that are not to be found or suggested by the Paton et al. reference (or separately by the Tamura reference). For anticipation to be found, all of the claimed elements must be found in Paton et al. (or separately in Tamura). Since that is not the case with respect to each and every one of the claims 1 – 20, the Examiner is respectfully asked to withdraw the rejection of these claims under 35 U.S.C. 102(b) and 102(e) and to consider allowance of the claims on this basis alone.

However, in consideration of the Examiner's remarks, and to facilitate further understanding of the functionality of the two separate indicators, claims 1 and 11 are amended to indicate that the irreversible cumulative time-temperature indicator integrates a time-temperature profile of the article/product under expected ambient storage conditions and the irreversible thermal event indicator indicates when the article/product has been exposed to very high temperatures that exceed the thermal limits of the article/product. These amendments are set forth and supported in the specification on page 7, lines 1-2 and page 8, lines 1-2 and 5-8, respectively. Consequently, new matter is not being added.

Recognizing that this response is after a Final Rejection, Applicant believes that any amendments to the claims in this response, which will place the case in condition for allowance, do not raise any issue of new matter and do not present new issues requiring further consideration or search. Since these amendments are now being offered after consideration of the Examiner's response to Applicant's prior arguments, and in order to facilitate further understanding of the functionality of the two separately claimed indicators, these circumstances should constitute a sufficient showing of good and sufficient reasons as to why the amendments are now necessary and were not earlier presented. Thus, these amendments are believed to comply with the requirements in 37 CFR 1.116 for the entry of an amendment after a final rejection, thereby placing the case in condition for allowance or, at the minimum, in better form for consideration on appeal.

If there are any formal matters remaining after this response, Applicants' attorney would appreciate a telephone call to attend to these matters.

In view of the foregoing it is respectfully submitted that the claims are in condition for allowance and such action is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul A. Leipold", written over a horizontal line.

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If the Examiner is unable to reach the Applicant(s) Attorney at the telephone number provided, the Examiner is requested to communicate with Eastman Kodak Company Patent Operations at (585) 477-4656.